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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/500,531 | 06/30/2004 | Shouqin Zhang | LUNGBJ/105/PC/US | 4346 |

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| EXAMINER | |
|---|---|
| DAVIS, RUTH A | |
| ART UNIT | PAPER NUMBER |
| 1651 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/29/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

TH

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/500,531 | ZHANG, SHOUQIN | |
| | Examiner | Art Unit | |
| | Ruth A. Davis | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's amendment and response filed on November 8, 2006 have been received and entered into the case. Claims 18 – 20 are added; claims 1 – 20 are pending and have been considered on the merits. All arguments have been fully considered.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 – 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for extraction small molecules from biological materials. However, the specification fails to set forth a representative number of examples in order to reasonably verify possession of such a potentially enormous number of molecules.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics, with respect to *all* molecules from all biological materials. The possible variations of small

molecules are limitless. Although the specification has disclosed 3 molecules that could be extracted by the claimed method, such a disclosure is actually *very few* in number as compared to the enormous, *potentially millions* of types of small molecules which could be obtained from biological materials.

The MPEP states that the purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter later claimed by him or her. The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, the specification fails to provide adequate written description for the genus of 'small molecules from biological materials and does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the entire scope of the claimed invention at the time the application was filed. Thus, the written description requirement has not been satisfied.

Applicant argues that it is known in the art to extract small molecules with heat and decocting, however the claimed invention speeds the process without use of heat and is therefore described for all small molecules.

However, these arguments fail to persuade because as stated above, the specification does not provide a description of the full scope of the claimed invention. Since the claims do not limit the biological material or small molecular ingredient, other than by weight, it is maintained that

the full scope of the claim encompasses such a large number of molecules and/or extracts, and that the specification fails to provide adequate written description for the claimed genus of small molecules. Moreover, the specification does not convey to one of ordinary skill in the art that the inventors had possession of the entire scope of the claims.

3. Claims 1 – 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for extracting flavonoids, polyphenols and baicalein from ginkgo leaves, tea leaves and Radix, respectively, does not reasonably provide enablement for a method for extracting small molecules from biological materials. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to a method for extracting small molecular ingredients from biological materials under super high pressure. As such, the claims encompass a wide variety of molecules from an innumerable number of biological materials. However, the specification fails to teach one in the art how to practice the method with any biological material and any small molecule. High pressure treatment is commonly used in the food art to inactivate microorganisms and enzymes (biological materials) (see attached "High pressure treatment of foods") and it is known in the art that high pressure treatment will inactivate prions (proteins) (see Brown et al.). Thus the state of the art suggests that applying super high pressure to some biological materials will in fact, damage the molecular structures of molecular components. Moreover, it would require an undue burden of experimentation for one in the art to determine

what small molecular compounds could be successfully extracted from what biological materials, by applying super high pressure as claimed.

Applicant argues that the examiner has failed to address each of the wands factors required in a lack of enablement rejection. Applicant further argues that the cited references use both high pressure and temperatures, not high pressure alone and that they do not disclose extraction small molecules with less than 10000 molecular weight.

Regarding the wands factors, it is noted that the above rejection does, in fact, address these factors, albeit without specific notation. For applicant's edification, these factors will be reiterated as follows:

Breadth of the claims – The claims are drawn to a method for extracting small molecular ingredients from biological materials under super high pressure. As such, the claims encompass a wide variety of molecules from an innumerable number of biological materials. This encompasses extraction of an enormous number of molecules, as the starting material is in no way limited. It is unquestionable that the claims are broad generics, with respect to molecules with a molecular weight of 10,000 or less from all biological materials. The possible variations of small molecules are limitless.

Nature of the invention – The claimed invention is drawn to a method for extracting small molecular component by way of high pressure

State of the prior art – The prior art recognizes that high pressure can be applied to biological materials to inactivate, or destroy, microorganisms and enzymes. It is also known that high pressure treatment will inactivate prions (proteins) (see Brown et al.). Thus, the prior art

recognizes that such methods may destroy such small molecular ingredients with MW of less than 10,000. It is noted that applicants includes enzymes and proteins as such small molecular ingredients (spec, p.1).

Level of ordinary skill in the art – One of ordinary skill in the art would understand in reading the cited references that applying high pressure (and heat as later claimed) to a biological material may inactivate or damage the molecular structure of some molecular ingredients such as enzymes and proteins.

Level of predictability in the art – The art suggests that applying super high pressure to some biological materials will in fact, damage the molecular structures or molecular components, while leaving others intact. Therefore, it is unpredictable which components will withstand the pressure and which will be damaged.

Level of direction provided by the specification – The specification teaches a method for extracting flavonoids, polyphenols and baicalein from ginkgo leaves, tea leaves and Radix, respectively. However, the specification fails to teach any other small molecular ingredient with a MW of 10000 or less that is successfully extracted from a biological material

Presence of working examples – The specification provides examples for extracting flavonoids, polyphenols and baicalein from ginkgo leaves, tea leaves and Radix, respectively

Quantity of experimentation needed to practice the claimed invention – as exemplified by the cited references and the minimal examples provided by applicant, applying pressure to a biological material may either damage and inactivate small MW ingredients, or may successfully extract the ingredient. Since the method has been disclosed in the art to be damaging, it would require an undue burden of experimentation for one in the art to determine what small molecular

compounds could be successfully extracted from what biological materials, by applying super high pressure as claimed.

Regarding applicant's assertion that the references apply both high pressure and heat, it is noted that the method is not limited to only high pressure, and that later claims in fact *require* heating in addition to the high pressure. Furthermore, the cited references clearly suggest to one in the art that applying super high pressure to biological materials may be damaging to enzymes and proteins (many of which may have MW of 10000 or less).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2 – 3, 5 – 9, 11 and 12 – 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 13 are drawn to a method for extracting small molecular components, however are rendered vague and indefinite because it is unclear if the method further comprises the claimed step or rather comprises the claimed step.

In claims 2 and 12, "the mixture" as recited in lines 2 and 3, respectively is confusing as it is unclear if the mixture is referring to the first (line 6) or second mixture (line 17) of claim 1.

Claims 3, 18 and 19 are confusing for reciting "done in steps" and "performed in steps" as it is unclear what steps are practiced to meet the limitation of the claim.

Claim 5 is confusing for reciting "container in a pulse type fashion" in line s 2 – 3, because there is a grammatical disconnect in the phrase. It is unclear what applicant intends to encompass by the claim.

Claim 6 is confusing for reciting "are independently chosen" because it is unclear if this means the solvents are required to be different, the same, or either.

In claims 7 and 9, it is unclear what the "other processing technologies" are meant to include.

In claim 8, it is unclear to what the phrase "devices" refers.

In claim 11, "the medium" lacks sufficient antecedent basis.

In claims 14 - 16, it is unclear if a heater and cooler is placed in a pressure container, or if the pressure container itself is heated and/or cooled.

Claim 15 fails to end with a period.

In claim 17, it is unclear how closing the container may occur before adding a mixture into the container.

the term "charging" has not been adequately defined by the claim language or specification.

It is further noted that claims 8, 11 and 17 are so confusing, vague and indefinite that they have not been able to be interpreted by the examiner.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1 – 3, 6, 10 – 13 and 17 – 19 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 04244203.

Applicant appears to claim a method for extracting small molecular components with MW of less than 10,000 from biological materials, the method comprising pulverizing a biological material with a solvent; placing the resulting mixture into a container; increasing the pressure from normal to 100 – 1000MPa at +/- 5C of room temperature; holding the mixture under pressure for 3 – 30 minutes; releasing the pressure to normal; and removing the mixture. The mixture is poured into an airtight packing container which is then placed into a pressure container; the steps of increasing, holding and releasing pressure are accomplished by a single or multiple steps; the multiple steps are accomplished by crushing the biological material with solvent and extracting under super high pressure, combining the resulting material with more solvent and extracting again under super high pressure; the solvent is water, an organic solvent or a mixture thereof and the biological material further comprises additives.

JP 04244203 teaches a method for extracting rice bran (biological material), wherein the rice bran is combined with amylase and a solvent and treated with 800MPa pressure for 60 minutes (abstract).

The reference anticipates the claimed subject matter.

Applicant argues that the reference teaches heating under pressure.

However, this argument fails to persuade because the claims also require heating (cl.14). Thus, the reference teaches the claimed invention.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 04244203, JP 09140337 or JP 04256405.

Applicant appears to claim a method for extracting small molecular components from biological materials, the method comprising pulverizing a biological material with a solvent; placing the resulting mixture into a container; increasing the pressure from normal to 100 – 1000MPa within 5C of room temperature; holding the mixture under pressure for 3 – 30 minutes; and releasing the pressure to normal. The mixture is poured into an airtight packing container which is then placed into a pressure container. The steps of increasing, holding and releasing pressure are accomplished by a single or multiple steps, specifically via ladder type or pulse type. The multiple steps are accomplished by crushing the biological material with solvent and extracting under super high pressure, combining the resulting material with more solvent and

extracting again under super high pressure; the mixture obtained from the method can be further processed; the biological material can be pretreated; the solvent is water, an organic solvent or a mixture thereof; the biological material further comprises additives; the extraction is performed under heating or cooling and the pressure container is placed in a cooler.

JP 04244203 teaches a method for extracting rice bran (biological material), wherein the rice bran is combined with amylase and a solvent and treated with 800MPa pressure for 60 minutes (abstract).

JP 09140337 teaches a method for extracting kombu seaweed (biological materials), wherein the seaweed is cut and combined with ionic water (or pretreated by crashing and formulation with a solvent); placed in a pressing vessel (the step of closure); and is placed under 50 – 200 MPa pressure (steps of increasing, holding, releasing pressure) (abstract).

JP 04256405 teaches a method for extracting biomass (biological material) comprising suspending the biomass (with a solvent) and treating with high pressure of more than 300 MPa, wherein the resulting product is further clarified.

The references do not teach that pressure is applied in the manner claimed, that the mixture is further processed, wherein the process occurs multiple times, or wherein heat or cooling is applied. However, at the time of the claimed invention, such steps were routinely practice in the art when extracting substances under high pressure. Thus, at the time the claimed invention was made, it would have been well within the purview of one of ordinary skill in the art to optimize the various parameters of the methods, to include the manner by which pressure is applied, how often and under cool/heated conditions, as a matter of routine experimentation.

Applicant argues that the references do not teach the method at room temperature, extraction during high pressure, or that the references require heating in addition to high pressure, thus teach away.

However, these arguments fail to persuade because applicant cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding applicant's assertion that the references require both heating and high pressure, it is noted that the claims also require heating (claim 14) thus it is clear from the teachings of the prior art that the claimed method is disclosed and suggested to one in the art.

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

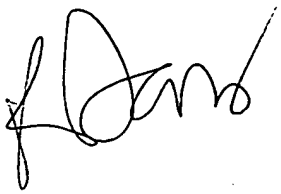
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis
Primary Examiner
Art Unit 1651



January 19, 2007